## 2021-05 Integrated Trial Matching for Cancer Patients and Providers

- **Short Description**
  - The purpose of this track is to test the implementation guide for the Integrated Trial Matching for Cancer Patients and Providers use case and to demonstrate the work being done for this project.

- **Long Description**
  - The purpose of this use case is to create a more equitable environment for patients and providers to find clinical trials. Currently, existing patient-facing and tools for clinical trial matching typically require a challenging amount of manual clinical data entry and/or manual review of trials. Additionally, providers do not have tools built in their workflow to allow for efficient clinical trial matching. As a result, providers often have to use the same patient-facing tools and manually enter data and/or manually review trials. As a result, this project aims to develop open data standards based on mCODE and open APIs that enable interoperable, scalable, and accessible clinical trial matching services. An implementation guide has been created to describe how matching services can become mCODE-enabled, which we would like to test during this Connectathon.

- **Type**
  - Test an Implementation Guide

- **Submitting Work Group/Project/Accelerator/Affiliate/Implementer Group**
  - This project is being conducted under the CodeX FHIR Accelerator and is sponsored by the Biomedical Research and Regulation Workgroup.

- **Track Lead(s)**
  - Caroline Potteiger
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- **Track Lead Email(s)**
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- **Related Tracks**

- **FHIR Version**
  - FHIR R4

- **Specification(s) this track uses**
  - [http://build.fhir.org/ig/standardhealth/fsh-pct/index.html](http://build.fhir.org/ig/standardhealth/fsh-pct/index.html)

- **Artifacts of focus**
  - OperationDefinition - Clinical Trial Match Service
  - Profile - TrialMatchDataBundle
  - Profile - TrialMatchResultSet
<table>
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<tr>
<th>Expected participants</th>
<th>MyLinks, MITRE, partners of this project</th>
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<td>Track Details</td>
<td>Document describing the scenarios</td>
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**System roles:**

- **Provided Resources:** FHIR server with synthetic mCODE records, FHIR server that supports the Clinical Trial Matching Service Operation, Integrated Trial Matching for Cancer Patients and Providers IG: [http://build.fhir.org/ig/standardhealth/fsh-pct/index.html](http://build.fhir.org/ig/standardhealth/fsh-pct/index.html)

- **Type of system that could participate in the track:** clinical trial matching services, any interested FHIR developer.

**Advanced preparation:** For Scenario 2, a sandbox endpoint should be available. Additionally, for Scenario 2, mCODE enabling a matching service to the specification in the IG can be a lengthy process. As a result, significant effort in starting the process of creating the wrapper (using the resources on git hub) prior to the start of the Connectathon will be helpful (resources listed below).

**Scenario 1 Name:** Patient uses their mCODE record to request and receive potential clinical matches

**Scenario 1 Summary:**

Lucy is a breast cancer patient looking for potential clinical trials in which she could participate. She uses her patient application to pull her mCODE record from her provider. She then uses her patient application to execute a search for clinical trials using her patient record. She receives back a set of clinical trials that are potential matches.

**Scenario 1 Actions:**

1. Pull patient’s mCODE medical record from the provided server with synthetic mCODE records, or start/create a hard coded mCODE record containing the optimized patient data elements outlined in the IG.
2. Using the patient record, construct a patient bundle that is compliant with the Clinical Trial Matching Service Input: Trial Match Data Bundle defined in the IG.
3. Send the constructed patient bundle to provided endpoint that supports the Clinical Trial Matching Service Operation, requesting a set of clinical trials that are potential matches to the patient profile.
4. Receive the Trial Matching Service Output: Trial Match Result Set from the endpoint, and display the clinical trial matching results contained in the SearchSet Bundle.

**Scenario 1 Precondition:**

Lucy’s mCODE patient record is available, either on a FHIR server or as file. There is a FHIR server that supports the Clinical Trial Matching Service Operation.

**Scenario 1 Success Criteria:**

The Integrated Trial Matching for Cancer Patients and Providers IG is used to construct a Trial Match Data Bundle that is used to request, receive, and display the Trial Match Result Set from the server supporting the Clinical Trial Matching Service Operation.

**Bonus point:**

1. Construct and add additional mCODE resources to the patient record (referencing the mCODE IG: [https://hl7.org/fhir/us/mcode/STU1/](https://hl7.org/fhir/us/mcode/STU1/)).
2. Filter/organize the Trial Match Result Set using any of the required fields of its ResearchStudy resources (Title, Phase, Study Type, etc.) as indicated by the IG.

**TestScript(s):**

**Test 01:** Lucy pulls her mCODE patient record.

- Request Asserts
  - Validate the GET of the patient’s mCODE record.
- Response Asserts
  - HTTP response code is 200
  - HTTP response body is the full patient record, containing all available mCODE.

**Test 02:** Lucy makes the request for potential clinical trial matches using her mCODE patient record.

- Request Asserts
  - Validate the POST of the Trial Match Data Bundle that contains the patient’s mCODE record.
- Response Asserts
  - HTTP response code is 200
  - HTTP response body is the Trial Match Result Set containing the potential clinical trial matches.
**Scenario 2 Name:** A client wants to mCODE enable their matching service by creating a matching service wrapper

**Scenario 2 Summary:**

A client has a matching service and wants to be able to handle mCODE records that can be used to perform an automated matching search in accordance with the Clinical Trial Matching Service Operation as defined in the Integrated Trial Matching for Cancer Patients and Providers IG. The client must build a wrapper that takes in the bundle of patient data (mCODE resources) and a FHIR Parameters resource. That bundle can then be used to fit the matching needs of the matching service. Once the match is performed, the results are then mapped to a SearchSet Bundle of FHIR ResearchStudy resources. The SearchSet Bundle is then returned.

**Scenario 2 Actions**

1. A client retrieves an mCODE record from the server and inputs two FHIR Parameters
   - ZipCode
   - SearchRadius
2. A client then compiles the mCODE record and FHIR Parameters into a Trial Match Data Bundle (FHIR) as defined in the IG via POST request to a matching service wrapper.
3. The matching service wrapper takes in the FHIR Bundle and then maps the resources to what is needed for performing a match inside of the matching service.
4. The request is then made to the matching service and the match is performed. The results are returned.
5. The results from the matching service are mapped to a SearchSet Bundle of FHIR ResearchStudy resources, as defined in the IG as a Trial Match Result Set.
6. The SearchSet Bundle of FHIR ResearchStudy resources are returned from the service wrapper.

**Scenario 2 Precondition:**

The client's record is in mCODE and on a server and a matching service exists.

**Scenario 2 Success Criteria:**

The client is able to see the results from the matching service displayed as a SearchSet Bundle of FHIR ResearchStudy resources.

**Bonus point:**

Leverage the clinical-trial-matching-engine UI to complete actions 1 and 2, and display the results from action 6

**TestScript(s):**

**Test 01:** The patient data bundle is received inside of the service wrapper and then compiled into a proper format for the matching service

Asserts:

- Validate the received FHIR Bundle has the patient data and Parameters resource
- Perform the mapping to match the format of the matching for the matching service
- Validate the results are returned from the matching service

**Test 02:** The results from the matching service are mapped to a FHIR Bundle of ResearchStudy resources

Asserts

- Validate the results are returned from the matching service
- Perform the mapping of each result to a FHIR ResearchStudy
- Validate that a SearchSet Bundle is created of FHIR ResearchStudy resources

**Test 03:** The patient data bundle is created and sent to the matching service wrapper

Asserts

- Request Asserts
  - Validate the FHIR Bundle has the patient data and Parameters resource and is sent to the wrapper via a POST request
- Response Asserts
  - HTTP response code is 200
  - HTTP response body contains the FHIR Bundle of FHIR ResearchStudy resources

**Security and Privacy Considerations:**

SMART-ON-FIRE use is assumed but could test without it if a server supports that.

**Resources:**

- [https://github.com/mcode/clinical-trial-matching-service](https://github.com/mcode/clinical-trial-matching-service) is a library that contains helper functions that can be used for building the ResearchStudy bundle.
- [https://github.com/mcode/clinical-trial-matching-service-template](https://github.com/mcode/clinical-trial-matching-service-template) is a template service wrapper that is a stubbed-out node server. It contains instructions on what is necessary to fill out and how to handle the results that are returned from a matching service.
- [https://github.com/mcode/clinical-trial-matching-engine](https://github.com/mcode/clinical-trial-matching-engine) is a SMART-ON-FHIR Angular app that can be used as a UI to pull a record from a FHIR server (R4) and send the bundle of patient data and FHIR Parameters to the service wrapper.
Slides Presented During the Connectathon:

Kickoff - 20210518_Connectathon_Touchpoint.pptx
Introduction - 20210518_Connectathon_Touchpoint.pptx
MyLinks Demo - 20210518_Connectathon_MyLinks_Demo.pptx